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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,648	04/11/2001	Cy A. Stein	0575/55669-Z/JPW/BJA	2605

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EXAMINER

EPPS FORD, JANET L

ART UNIT	PAPER NUMBER
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1633

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/832,648

Applicant(s)

STEIN, CY A.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9,26-30,36-52 and 54-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9,26-30,36-52 and 54-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7-19-04, 5-23-05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claim 36 and 38 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 9 and 37, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).
3. The rejection of claims 37-45, 55, 58, and 63-65 under 35 U.S.C. 103(a) as being unpatentable over Pollman et al. and Gibbons et al. (US Patent No. 5,776,905) in view of Agrawal, and Summerton, is withdrawn in response to Applicant's amendments and arguments filed 7-19-04.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 39-50, and 54-61 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (Written Description).

Applicant's arguments filed 7-19-04 have been fully considered but are not persuasive. Applicants traverse the instant rejection on the grounds by way of amending the claims to require that the antisense compounds are complementary to a bcl-xl mRNA. The claims remain rejected for the reasons of record since Applicants have not defined the term "complementary" in either the specification as filed or in the claims. Therefore, the scope of the term "complementary" may encompass wherein the claimed antisense oligonucleotide comprises a region wherein it is complementary to a bcl-xl mRNA, or wherein the entire oligonucleotide is complementary to a bcl-xl mRNA. Moreover, Applicant's have not included any specific sequence defining "a bcl-xl mRNA." Thus the scope of the term "a bcl-xl mRNA," may encompass all allelic and polymorphic variant forms of bcl-xl mRNA. As stated in the prior Office Action, apart from further experimentation the skilled artisan would not be able to envision the structures of the full scope of compounds encompassed by the instant claims. Therefore, Applicants were not in possession of the full scope of the claimed compounds at the time of filing of the instant invention.

#### ***Double Patenting***

6. Claims 9, 26-30, 36, 63, and 65, remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-54, and 61-62 of copending Application No. 10/160,344.

7. Claims 37-52, 54-62, were previously amended. The original claims were identical to those set forth in copending application 10/160,344. The current amendment to the instant claims, to require at least one 2'-Ome modification renders

the scope of these claims obvious over copending claim 47 which requires at least one sugar modification. Instant claims 51-52 remain identical in scope to copending claims 51-52.

8. Applicant's arguments filed 7-19-2004, have been fully considered, but are no persuasive. Applicants traversed the instant rejection on the grounds that the claims of the copending application do not recite wherein the oligonucleotides comprise one or more sugar modifications at its 2' position. Contrary to Applicant's assertions, claim 47 of the copending application, recites wherein the oligonucleotides claimed in claims 37-43 comprise at least one modified sugar moiety. This claim clearly renders the instant, which recite the same antisense oligonucleotides comprising at least one sugar modification.

***New Grounds for rejection:***

***Claim Rejections - 35 USC § 112***

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 64, 66-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 66-72 depend from cancelled claim 1. Claims 66-72 lack of antecedent basis for the limitations recited in claim 1, since Applicants canceled this claim.

11. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between

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the elements. See MPEP § 2172.01. The omitted elements are: The method comprises introducing into a vascular cell an amount of an antisense oligonucleotide. However, the method does not require that the vascular cell be a vascular cell that is part of the vascular lesions, wherein the regression is to be promoted. The instant method lacks the element wherein there is a clear nexus between the vascular cell treated corresponds to the vascular lesion that is to be treated.

***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 62 is rejected under 35 U.S.C. 102(e) as being anticipated by Yoshida et al. (US Patent No. 5,843,713).

Claim 62 is drawn to an oligonucleotide comprising 10 or more contiguous bases of a sequence selected from a group that includes SEQ. ID. NO: 6, or the nucleotide sequence according to "F" of Figure 1.

Yoshida et al. disclose an oligonucleotide consisting of SEQ. ID. NO: 90, where bases 28-40 of the sequence disclosed by Yoshida et al. are identical to bases 6-18 of SEQ ID. NO: 6 of claim 62. Although the preamble of claim 62 recites a different intended use (antisense) than Yoshida et al. disclose for their oligonucleotide, the recitation of an intended use in the preamble is seen as non-limiting since all other structural limitations are met (MPEP 2111.02). Since the structure recited by Yoshida et al. meets the claimed structural limitations, the function recited in the preamble is presumed to be an inherent property (MPEP 2112.01).

15. Claims 52 and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown et al. (US Patent No. 5,689,052).

Claims 52 and 62 are drawn to an oligonucleotide comprising 10 or more contiguous bases of a sequence selected from a group that includes SEQ. ID. NO: 7, or the nucleotide sequence according to "G" of Figure 1.

Brown et al. disclose an oligonucleotide consisting of SEQ. ID. NO: 28, where bases 3-14 of the sequence disclosed by Brown et al. are identical to bases 5-16 of SEQ ID. NO: 7 of claims 52 and 62. Although the preamble of claims 52 and 62 recite a different intended use (antisense) than Brown et al. disclose for their oligonucleotide, the recitation of an intended use in the preamble is seen as non-limiting since all other structural limitations are met (MPEP 2111.02). Since the structure recited by Brown et

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al. meets the claimed structural limitations, the function recited in the preamble is presumed to be an inherent property (MPEP 2112.01).

16. Claims 52 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Lam et al (US Patent No. 5,496,547).

Claims 52 and 62 are drawn to an oligonucleotide comprising 10 or more contiguous bases of a sequence selected from a group that includes SEQ. ID. NO: 7, or the nucleotide sequence according to "G" of Figure 1.

Lam et al. disclose an oligonucleotide consisting of SEQ. ID. NO: 4, where bases 17-30 of the sequence disclosed by Lam et al. are identical to bases 6-19 of SEQ ID. NO: 7 of claims 52 and 62. Although the preamble of claims 52 and 62 recite a different intended use (antisense) than Lam et al. disclose for their oligonucleotide, the recitation of an intended use in the preamble is seen as non-limiting since all other structural limitations are met (MPEP 2111.02). Since the structure recited by Lam et al. meets the claimed structural limitations, the function recited in the preamble is presumed to be an inherent property (MPEP 2112.01).

17. Claim 62 is rejected under 35 U.S.C. 102(b) as being anticipated by Levitt (WO 95/15400).

Claim 62 is drawn to an oligonucleotide comprising 10 or more contiguous bases of a sequence selected from a group that includes SEQ. ID. NO: 9, or the nucleotide sequence according to "I" of Figure 1.

Levitt et al. disclose an oligonucleotide having the sequence shown in Fig. 7E-3, last sequence, where bases 5-20 of the sequence disclosed by Levitt et al. are identical



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to bases 2-17 of SEQ ID. NO: 9 of claim 62. Although the preamble of claim 62 recites a different intended use (antisense) than Levitt et al. disclose for their oligonucleotide, the recitation of an intended use in the preamble is seen as non-limiting since all other structural limitations are met (MPEP 2111.02). Since the structure recited by Levitt et al. meets the claimed structural limitations, the function recited in the preamble is presumed to be an inherent property (MPEP 2112.01).

18. Claim 62 is rejected under 35 U.S.C. 102(e) as being anticipated by Reed et al. (US Patent No. 5,702,897).

Claim 62 is drawn to an oligonucleotide comprising 10 or more contiguous bases of a sequence selected from a group that includes SEQ. ID. NO: 13, or sequence M of Figure 1.

Reed et al. disclose an oligonucleotide consisting of SEQ. ID. NO: 11, where bases 4-20 of the sequence disclosed by Reed et al. are identical to bases 2-18 of SEQ ID. NO: 13 of claim 62. Although the preamble of claim 62 recites a different intended use (antisense) than Reed et al. disclose for their oligonucleotide, the recitation of an intended use in the preamble is seen as non-limiting since all other structural limitations are met (MPEP 2111.02). Since the structure recited by Reed et al. meets the claimed structural limitations, the function recited in the preamble is presumed to be an inherent property (MPEP 2112.01).


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19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 9:30 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 517-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
Janet L. Epps-Ford  
Examiner  
Art Unit 1633

JLE